

12 CV 778
10/18/12UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----- X
PRESTIGE BRANDS, INC., and BLACKSMITH :
BRANDS, INC., : Civil Action No.
Plaintiffs, :
v. :
GUARDIAN DRUG COMPANY, : JURY TRIAL DEMANDED
Defendant. :
----- X

COMPLAINT

Plaintiffs Prestige Brands, Inc. ("PBI") and Blacksmith Brands, Inc. ("Blacksmith") (collectively "Prestige"), hereby set forth their Complaint for relief against Guardian Drug Company ("Guardian"), showing the Court as follows:

INTRODUCTION

1. Prestige markets, sells, and distributes over-the-counter healthcare products to retail outlets in the U.S., Canada, and certain international markets. Prestige's brands include Chloraseptic®, Clear Eyes®, Dramamine®, Efferdent®, Little Remedies®, Luden's®, PediaCare®, BC®, and Goody's®.

2. For a period of time, acting as a contract manufacturer, Guardian manufactured for Prestige PediaCare® Infants Fever Reducer/Pain Reliever Acetaminophen, PediaCare® Infants Gas Relief Drops, and Little Fevers® Children's Fever/Pain Reliever Acetaminophen.

3. Guardian supplied products to Prestige pursuant to purchase orders. The purchase orders contained standard terms and conditions, which, among other things, required Guardian to supply product to Prestige that was free from all defect and to indemnify Prestige

for losses caused by defects in the products supplied or for any similar failure of performance by Guardian. The PBI standard terms and conditions are attached hereto as Exhibit A and the Blacksmith standard terms and conditions are attached hereto as Exhibit B.

4. Towards the end of 2011, certain quality control issues at Guardian's manufacturing plant manifested themselves as material defects in the products Guardian supplied to Prestige, namely the PediaCare® Infants Fever Reducer/Pain Reliever Acetaminophen, PediaCare® Infants Gas Relief Drops, and Little Fevers® Children's Fever/Pain Reliever Acetaminophen products. More specifically, on 3 separate occasions, the products that Guardian supplied to Prestige were subject to recall. These recalls were necessary to comply with requirements of the U.S. Food and Drug Administration ("FDA").

5. Each recall caused by Guardian's manufacturing required Prestige to incur considerable expense and to suffer significant loss. These losses extended beyond the loss of the recalled product, which regulations required Prestige to destroy, and encompassed fines, fees, and reimbursements Prestige paid its retail customers. In addition, the recalls generated expenses for labor and transportation, which fell squarely on Prestige.

6. Because the losses Prestige suffered resulted from defects in the products Guardian supplied, Prestige looked to Guardian to provide indemnity. Guardian refused and still refuses to honor that obligation. As a result, Prestige has been forced to bring this action to receive the benefit of its bargain.

THE PARTIES, JURISDICTION AND VENUE

7. PBI is a corporation duly organized and existing under the laws of the State of Delaware, with its principal place of business at 660 White Plains Road, Suite 205, Tarrytown, New York 10591.

8. Blacksmith is a corporation duly organized and existing under the laws of the State of Delaware, with its principal place of business at 660 White Plains Road, Suite 205, Tarrytown, New York 10591.

9. Guardian is a New Jersey corporation, with its principal place of business at 2 Charles Court, Dayton, New Jersey 08810.

10. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332, because complete diversity exists among the parties and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

11. Venue is proper in the Southern District of New York pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the claim occurred in this district and because Guardian consented to jurisdiction in this district by agreeing to the standard terms and conditions attached hereto as Exhibit A.

FACTS

12. Prestige markets, sells, and distributes over-the-counter healthcare products to retail outlets in the U.S., Canada, and certain international markets. Prestige's brands include Chloraseptic®, Clear Eyes®, Dramamine®, Efferdent®, Little Remedies®, Luden's®, PediaCare®, BC®, and Goody's®.

13. Guardian manufactured and packaged for Prestige the following products: PediaCare® Infants Fever Reducer/Pain Reliever Acetaminophen, PediaCare® Infants Gas Relief Drops, and Little Fevers® Children's Fever/Pain Reliever Acetaminophen.

14. Guardian supplied these three products to Prestige pursuant to terms contained in purchase orders. Each purchase order provided key contract terms, including, among other things, the product description, the number of units sold and the price per unit.

15. The purchase orders between Prestige and Guardian that governed Prestige's purchase of and Guardian's supply of most of the PediaCare® and all of the Little Fevers® products at issue incorporated terms in an attached "Purchase Order Terms and Conditions" (the "PBI Terms and Conditions"). A copy of the PBI Terms and Conditions is attached hereto as Exhibit A.

16. Pursuant to the PBI Terms and Conditions, Guardian agreed to, among other things:

- a. supply products that were "free from all defects in materials, workmanship, design, and fabrication";
- b. supply products that were "merchantable and of high quality" and "were fit for [Prestige's] intended purpose or use";
- c. supply products that "were manufactured and packaged in accordance with all applicable laws"; and
- d. "indemnify, defend and hold harmless [Prestige]" and "its affiliated companies . . . from any and all liability, loss, claim, action, demand, settlement, cost or expense of any type (including without limitation, attorneys' fees) arising out of or in any way connected with," among other things, "[Guardian]'s (or any subcontractor's) performance under any controlling contract and/or this Purchase Order."

17. The purchase orders between Prestige and Guardian that governed Prestige's purchase of and Guardian's supply of some of the PediaCare® products at issue incorporated terms in a "Quality Agreement Rider" (the "Blacksmith Terms and Conditions"). A copy of the Blacksmith Terms and Conditions is attached hereto as Exhibit B.

18. Pursuant to the Blacksmith Terms and Conditions, Guardian agreed to, among other things, "produce the Products in accordance with all federal, state, and local regulations and applicable Good Manufacturing Practice regulations ... and the product specifications agreed upon by the parties."

19. Further, the Blacksmith Terms and Conditions provide that "in the event ... Customer shall determine to undertake, any corrective action with respect to Products supplied hereunder, ... including any Product recall, customer notice, restriction, change, corrective action or market action, or any Product change, and the cause or basis of such corrective action is directly attributable to any breach by Supplier of any of its representations, warranties, obligations, or covenants contained herein, then Supplier shall be liable, and shall reimburse Customer, for the costs of such action."

20. Guardian had certain quality control issues that caused Guardian to supply Prestige with PediaCare® products that failed to meet the requirements set forth in the PBI and Blacksmith Terms and Conditions and with Little Fevers® products that failed to meet the requirements set forth in the PBI Terms and Conditions.

Manufacturing Issues Recalls

21. Guardian manufactured and packaged for Prestige the PediaCare® Infants Fever Reducer/Pain Reliever Acetaminophen. Guardian's manufacture and delivery of this product failed to conform to the requirements of the PBI and Blacksmith Terms and Conditions because, among other reasons, the product was not free from all defects, was not merchantable and of high quality, and was not fit for Prestige's intended purpose.

22. Guardian manufactured and packaged for Prestige the Little Fevers® Children's Fever/Pain Reliever Acetaminophen. Guardian's manufacture and delivery of this product

failed to conform to the requirements of the PBI Terms and Conditions because, among other reasons, the product was not free from all defects, was not merchantable and of high quality, and was not fit for Prestige's intended purpose.

23. As a result of Guardian's failures, Prestige was forced to recall (a) PediaCare® Infants Fever Reducer/Pain Reliever Acetaminophen on March 13, 2012 and (b) Little Fevers® Children's Fever/Pain Reliever Acetaminophen on April 5, 2012.

24. Prestige incurred significant damages related to the recall of these two products manufactured by Guardian.

Guardian Initiated Recall

25. On March 7, 2012, Guardian contacted Prestige about a voluntary recall, which Guardian had initiated. The recall affected a product called PediaCare® Infant Gas Relief Drops.

26. Upon information and belief, Guardian had initiated the recall because the active ingredient used in the product was subject to a separate recall by Guardian's raw materials supplier.

27. The recall Guardian initiated forced Prestige, in turn, to recall PediaCare® Infant Gas Relief Drops and to incur significant damages associated with the recall.

Losses Suffered

28. With respect to each of the recalls above, Prestige incurred significant financial losses, including, but not limited to, losses it incurred:

- a. on the recalled products it was forced to destroy;
- b. to reimburse its customers – generally, retailers and hospital pharmacies – for all recalled products the customer returned or destroyed;

- c. to fund investigations and analyses of the products;
 - d. to pay fees and fines that resulted from the recall; and
 - e. as a result of lost sales of the product.
29. To this date, Guardian has failed to indemnify Prestige for any of the losses it suffered as a result of the recalls, in breach of its obligations.

COUNT ONE – BREACH OF CONTRACT

30. Prestige incorporates herein by reference paragraphs 1 through 29, above, as if fully set forth herein.

31. The PBI and Blacksmith Terms and Conditions obligate Guardian to indemnify Prestige for all losses associated with Guardian's failure to provide product that conforms to the requirements set forth in the PBI and Blacksmith Terms and Conditions.

32. Guardian failed to provide product that conformed to the requirements set forth in the PBI and Blacksmith Terms and Conditions when it supplied Prestige with products that were required to be recalled.

33. Prestige suffered significant losses in connection with those recalls.

34. Guardian has failed to indemnify Prestige for those losses, in breach of the PBI and Blacksmith Terms and Conditions.

35. Prestige has fully performed under the terms of the agreement.

36. Prestige has sustained damages as a result of the foregoing breach.

COUNT TWO – COMMON LAW INDEMNITY

37. Prestige incorporates herein the provisions of paragraphs 1 through 36, above, as if fully set forth herein.

38. Through its negligence, Guardian manufactured the PediaCare® and Little

Fevers® products with deficiencies that required the products be recalled.

39. Guardian was solely responsible for the manufacture of the recalled products and any defects therein.

40. The defects in the recalled products were the direct and immediate cause of the losses Prestige suffered as a result of the recalls.

41. Prestige reasonably relied on Guardian to manufacture products fit for their intended use and devoid of material defects.

42. Prestige suffered damages as a result of Guardian's failure to manufacture the products properly.

43. Guardian is responsible for the losses Prestige incurred as a direct result of Guardian's failure to manufacture the products properly and the resulting recalls on the products.

COUNT THREE – BREACH OF IMPLIED WARRANTY

44. Prestige incorporates herein the provisions of paragraphs 1 through 43, above, as if fully set forth herein.

45. Prestige purchased the recalled PediaCare® and Little Fevers® products from Guardian in order to resell those products to retailers of over-the-counter health products.

46. Guardian knew that Prestige intended to resell the recalled products and knew that the products were intended for human consumption in a regulated market.

47. Prestige justifiability relied on the skill and judgment of Guardian to manufacture products within the product specifications.

48. Guardian knew that Prestige was relying on its skill and judgment.

49. The recalled PediaCare® and Little Fevers® products fell below the minimums

set in the product specifications and, therefore, were not fit for resale.

50. Prestige notified Guardian within a reasonable time that the products were unfit for resale.

51. Prestige has sustained damages as a result of the foregoing breach.

WHEREFORE, having set forth its Complaint above, Prestige prays that this Court:

- (A) find Guardian liable under multiple theories for the wrongful acts described above and as may be otherwise proven at trial;
- (B) award compensatory damages sufficient, where possible, to compensate for the damage done;
- (C) award plaintiff its attorneys' fees and costs; and
- (D) provide such other and further relief as the Court deems just and proper.

Dated: New York, New York
October 18, 2012



Todd R. David
Lisa Bugni (*pro hac vice* to be filed)
Joe Tully
ALSTON & BIRD LLP
90 Park Avenue
New York, NY 10016-1387
(212) 210-9400

*Counsel for Plaintiffs Prestige Brands, Inc.
and Blacksmith Brands, Inc.*



PURCHASE ORDER TERMS AND CONDITIONS

- 1. Definitions.** The term "Seller" shall mean the party to whom this Purchase Order is addressed as set forth on the face of the Purchase Order. The term "Buyer" shall mean the party indicated on the face of the Purchase Order as the party submitting the Purchase Order to Seller. The term "Product" shall mean any article, material, or service set forth on the face of the Purchase Order.
- 2. Controlling Contract.** All terms and conditions of this Purchase Order are controlled by any controlling contract between Seller and Buyer, and, in the event of any inconsistency between the controlling contract and this Purchase Order, the controlling contract shall govern; provided, however, that in the event of such inconsistency, the controlling contract shall invalidate only the expressly inconsistent provisions contained herein and shall not affect any other or additional provisions contained in this Purchase Order even though such provisions may not appear in the controlling contract.
- 3. Acceptance of Terms.** By acceptance of this Purchase Order, Seller agrees to sell the Products to Buyer on the terms and conditions contained in any controlling contract and this Purchase Order. **ANY PROVISIONS OF ANY ACKNOWLEDGMENT FORM OR OTHER DOCUMENT PREPARED BY SELLER WHICH ARE IN CONFLICT WITH OR IN ADDITION TO THE PROVISIONS OF THIS PURCHASE ORDER SHALL NOT BIND BUYER UNLESS BUYER EXPRESSLY ASSENTS TO SUCH PROVISIONS IN WRITING.** Seller shall be deemed to have accepted the Purchase Order upon the earlier to occur of (a) Seller signing a copy of this Purchase Order, (b) any performance by Seller under this Purchase Order, or (c) ten days after Seller's receipt of this Purchase Order provided Seller does not reject such Purchase Order in writing within such ten day period. If Seller refuses to accept this Purchase Order exactly as written, Seller will immediately contact Buyer, and immediately return this Purchase Order along with an explanation.
- 4. Acknowledgement and Shipment.** Seller shall acknowledge this Purchase Order immediately by advising Buyer of when shipment will be made or services will be provided, and confirming method of shipment. Unless otherwise agreed, time is of the essence and immediate shipment/commencement of work is required. Notify at once of any delay. If a Purchase Order does not meet Seller's minimum billing, Seller shall promptly notify Buyer in which event Buyer reserves the right to either cancel or increase order.
- 5. Delivery/TITLE.** Unless otherwise agreed, delivery shall be F.O.B. origin/factory and title shall pass to Buyer upon delivery to Buyer's carrier at origin/factory. Risk of damages or loss during shipment shall be the responsibility of Buyer.
- 6. Inspection; Rejection.** Inspection by Buyer of the Product shall be at the Buyer's warehouse unless otherwise designated by Buyer. Buyer reserves the right to reject and refuse acceptance of items that are not in full accordance with Buyer's instructions, specifications, drawings or designs, as the case may be. Any Products not accepted by Buyer will be returned to Seller at Seller's expense for full credit. This inspection shall constitute conditional acceptance of the Product by Buyer and shall not waive the right of Buyer to return Products containing latent defects. Payment for an item shall not be deemed an acceptance thereof.
- 7. Warranties.** Seller warrants that (a) the Products delivered are free from all defects in materials, workmanship, design, and fabrication and conform to the specifications, drawings, samples, or other descriptions furnished to or by Buyer; (b) title to the Products is delivered to Buyer free and clear of all liens, rights, and encumbrances of all kinds; (c) the Products are free of any rightful claim of patent, trade name, trademark, copyright infringement, or similar proprietary rights of any third party; (d) the Products are merchantable and of high quality; (e) that the Products are fit for Buyer's intended purpose or use; and (f) the Products were manufactured and packaged in accordance with all applicable law (including, without limitation, the Federal Food, Drug and Cosmetic Act, as amended, the Federal Insecticide, Fungicide and Rodenticide Act, as amended, and applicable labor laws). Such warranty shall run in favor of Buyer, its successors and assigns, employees, customers, and users of Product. In addition to any and all other remedies provided to Buyer by law or equity, items found to be defective in workmanship or material after date of acceptance shall be repaired or replaced, at Buyer's option, at no charge to Buyer. All substitutions must be agreed to in writing prior to shipment. All freight charges involving the shipment of defective items shall be for Seller's account. Seller further warrants that all services will be performed in a professional and workmanlike manner.
- 8. Indemnification.** Seller agrees to indemnify, defend and hold harmless Buyer, its affiliated companies and each of their respective directors, officers, employees, agents and representatives from any and all liability, loss, claim, action, demand, settlement, cost or expense of any type (including, without limitation, attorneys' fees) arising out of or in any way connected with (i) a breach of any controlling contract and/or this Purchase Order; (ii) Seller's (or any subcontractor's) performance or non-performance under any controlling contract and/or this Purchase Order; (iii) alleged or actual infringement of third-party patents, trademarks, copyrights or applications; therefore, trade secrets or any other intellectual property or proprietary rights; or (iv) any violation of any statute, regulation or ordinance of any governmental authority in the manufacture, sale or delivery of the Products furnished or required to be furnished hereunder. Seller shall not agree to any settlement, without Buyer's written consent, unless such settlement fully relieves Buyer from any and all liability in connection with the claim underlying the settlement. Seller further agrees to pay Buyer's attorneys' fees and expenses incurred by Buyer in enforcing the foregoing indemnification provisions.
- 9. Buyer's Property.** All intellectual property, drawings, dies, patterns, equipment, designs, specifications, data or other items (collectively the "Property") supplied by the Buyer or supplied by the Seller at Buyer's expense shall be and remain the exclusive property of Buyer and shall be returned to Buyer upon termination or completion of any controlling contract and this Purchase Order. Seller assumes all risk of loss or of damage to such Property until it is returned to Buyer. Seller agrees that it will use such Property only in the production of the Products called for by this Purchase Order and not otherwise except with the written consent of Buyer. Seller shall not disclose the Property to any person, nor any other information pertaining to Buyer's affairs, except as is necessary for Seller to furnish the Products pursuant to this Purchase Order. Any information or technology contained in such Property shall be treated by Seller as being proprietary to Buyer and shall not be disclosed to any third party not having a need for such disclosure consistent with Seller's authorized use of such information.
- 10. Packing Charges.** No charges for boxing, packing, crating or pallets will be allowed unless agreed to in writing and signed by Buyer's authorized agent.
- 11. Identifying Numbers.** Purchase Order number and vendor number (and Buyer's stock number if shown on the Purchase Order) must appear on all packages, packing slips or correspondence pertaining to this order.
- 12. Bills of Lading and Shipping Memoranda.** All bills of lading and shipping memoranda must accompany the shipment.

13. **Invoices.** Invoices shall contain the following information: (i) Purchase Order number, item number, Buyer's stock number, description of supplies or services, sizes, quantities, unit prices and extended totals; and (ii) bill of lading number and weight of shipment for shipments shipped F.O.B. shipping point. All invoices must be issued in the same unit of measure as shown on this Purchase Order. Invoices must be sent to the address shown on the Purchase Order. Buyer shall not be responsible for delays caused by invoices being sent to the wrong address.

14. **Discounts.** In connection with any discount offered for prompt payment, the deadline for paying the discounted price will be calculated from the latest of: (i) date of delivery at destination or port of embarkation (when delivery and acceptance are at either of these points); or (ii) the invoice date is received in the office specified by Buyer. For the purpose of earning any such discount, payment will be deemed to be made on the date of Buyer's check.

15. **Changes.** Buyer may at any time, by written notice, make changes in: (i) drawings, designs, or specifications (where the items to be furnished are to be specially manufactured for Buyer in accordance therewith); (ii) method of shipment or packing; and (iii) time or place of delivery. If any such changes cause an increase or decrease in the cost of, or time required for, performance of this order, Seller shall advise Buyer of such increase or decrease. Buyer shall in turn advise Seller if it agrees that an adjustment will be made in the price or delivery schedule, or both.

16. **Variation in Quantity.** No variation in the quantity of any item set forth in this Purchase Order will be accepted unless agreed to in writing and signed by Buyer's authorized agent.

17. **Right to Audit.** If this Purchase Order involves services, repairs or materials that reflect a cost plus or unit pricing method of purchasing, all charges based on time, materials or third party rentals shall be subject to examination by Buyer, and Seller, upon request by Buyer, shall permit Buyer to examine its books and records in respect of all such charges.

18. **Default.** Any failure by Seller to perform any of its obligations under this Purchase Order, including, without limitation, timely delivery of Products, or the insolvency, assignment for the benefit of creditors, filing of a voluntary or involuntary petition under any bankruptcy law, appointment of a receiver or dissolution, liquidation, or winding up the business of Seller shall constitute a default; provided, however, that any delay in delivery hereunder arising out of causes beyond the control and without the fault or negligence of Seller shall NOT constitute a default by Seller. Upon the occurrence of any such default, Buyer may, at its option, exercise any remedy or right provided by law or available in equity, including without limitation, all remedies available under the laws of the State of New York, including the right to cancel any outstanding deliveries under this Purchase Order and to procure upon such terms and in such manner, as Buyer may deem appropriate, products similar to the Products ordered and Seller shall be liable to Buyer for any excess costs or expenses incurred by Buyer as a result of such procurement. Any action brought to enforce any remedy under this Purchase Order may be brought in the State and Federal Courts located Westchester County, New York and Seller hereby consents to the jurisdiction of such courts.

19. **Termination.** Buyer may terminate this Purchase Order, in whole or in part, at any time by written notice to Seller. The written notice shall state the extent and effective date of such termination. Upon receipt of such notice, Seller shall comply with the instructions in the notice. Buyer and Seller shall agree to the amount of fair compensation to Seller for termination, and, if the parties cannot agree within a reasonable time, Buyer shall pay to Seller (a) the contract price for the Products which have been completed, and (b) the actual cost incurred by Seller, which are properly apportionable under recognized commercial accounting practices to the terminated portion of the Products ordered pursuant to this Purchase Order. In no event shall Buyer be liable to Seller for any loss of profit or consequential damages or for more than the total contract price specified in the Purchase Order. Buyer shall have access to Seller's records to determine the validity of Seller's claim pursuant to this Section. In the event this Purchase Order is terminated as a result of Seller's default, Seller shall be liable for all damages allowed in law or equity, including Buyer's excess cost of procuring similar items.

20. **Governing Law.** This Purchase Order shall be governed and construed in accordance with the laws of the State of New York, without giving effect to the conflicts of law provisions thereof.

21. **Notice.** All notices permitted or required by this Purchase Order shall be in writing and shall be given by mail or personal delivery, including delivery by courier, addressed to the parties at their respective addresses as shown on the face of this Purchase Order or at such other addresses as either party may specify in writing. Notice given by mail shall be effective three days after the mailing of such notice. Notice given by personal delivery shall be effective upon receipt.

22. **Assignment.** Neither this Purchase Order nor any part of this Purchase Order may be assigned or delegated by Seller to any third-party.

23. **Severability.** In the event any of the provisions of this Purchase Order are declared unenforceable by a duly authorized court having jurisdiction, the remaining terms and provisions shall remain in full force and effect.

24. **Entire Agreement.** The terms and agreement contained herein express the complete agreement of the parties and no terms and conditions in any way modifying or in addition to the foregoing provisions shall be binding upon Buyer unless made in writing and signed by an authorized representative of the Buyer. This Purchase Order (and any controlling contract, if applicable) constitutes the entire agreement between Seller and Buyer, and no change in or modification of this Purchase Order shall be binding upon Buyer unless the change or modification is in writing and signed by Buyer. The terms and conditions as stated in this Purchase Order govern in the event of a conflict with any terms of any proposal by Seller and are not subject to change by reason of any written or verbal statements by Seller or by any terms stated in any acknowledgment or confirmation of Seller unless the same is accepted in writing signed by Buyer.



QUALITY AGREEMENT RIDER

Any purchase order by Blacksmith Brands, Inc. ("Customer") to which this rider is attached, as well as any purchase order that specifically includes or incorporates this rider by reference, shall be subject to the following provisions regarding quality control, regulatory requirements, and product inspection. Additionally, all products (the "Products") supplied under any such purchase order shall meet the minimum quality standards contained herein. The supplier ("Supplier") acknowledges and agrees that Supplier's promise to comply with the terms contained herein is necessary to induce Customer to submit any such purchase order and Supplier further acknowledges and agrees that Customer has relied upon Supplier's acceptance of the within terms in deciding to purchase the Products.

Quality Control

Compliance. Supplier shall produce the Products in accordance with all federal, state, and local regulations and applicable current Good Manufacturing Practice regulations (CFR 210 and 211) issued pursuant to the United States *Food, Drug and Cosmetic Act of 1938* (21 U.S.C. §§ 321 *et seq.*) ("cGMPs") and the product specifications (the "Product Specifications") agreed upon by the parties. Supplier represents and warrants to Customer that neither Supplier nor any of its employees have been "debarred" by the United States Food and Drug Administration ("FDA"), nor have debarment proceedings against Supplier or any of its employees been commenced or threatened. Supplier shall immediately notify Customer in writing if any such proceedings have been commenced or threatened or if Supplier or any of its employees are debarred by the FDA.

Raw Materials. Supplier shall verify that any raw materials used meet the Product Specifications. No Raw Materials shall be used that do not comply with the Product Specifications and all applicable laws, rules, or regulations. Customer's prior written approval shall be required for any deviation from the foregoing. All Raw Materials are to be rotated on a first in - first out basis. Supplier shall store all raw materials and finished Products in accordance with the Product Specifications in areas that are in compliance with federal and state regulations. Areas shall be clean, free from foreign material and controlled to prevent contamination. Appropriate pest control programs shall be in place to prevent contamination. Areas shall be monitored to ensure Product quality is not compromised.

Records. Supplier shall perform all raw material testing, as well as in process and finished Product testing, necessary pursuant to the Product Specifications to ensure product quality. All test results are to be documented and Supplier shall maintain production records for each batch of Product produced and shall retain samples of each batch thereof. Documentation shall include ingredient analysis, date of production, process control records, in-process analytical and inspection results, ingredient usage by lot, filling data, finished product analytical results, finished product microbiology test results and sanitation records, as applicable. Customer shall have the right to review and/or inspect any such records or samples at any time upon written request.

Disposal of Rejected Products. All Products rejected in accordance with the terms hereof shall be disposed of in a manner consistent with federal, state, and local regulations and such costs of disposal (and the costs of any raw materials used in any such rejected Products) shall be the responsibility of Supplier. No non-conforming Product or in process Product can be sold or donated, or otherwise disposed of for subsequent consumption, without written authorization from Customer.

Production Codes. Supplier's production codes shall be recorded and maintained according to Customer's guidelines unless otherwise agreed to by Customer. Lot traceability shall be in place from raw materials to final shipment of finished Products. Upon Customer's request, Supplier shall provide Customer, within a reasonable timeframe, complete lot information for tracking.

Facility. Supplier's manufacturing facility shall meet or exceed all applicable requirements established by federal, state, and local requirements, including but not limited to cGMPs as they relate to the Products. Supplier also agrees to make any changes to its facility and/or manufacturing processes necessary to comply with its obligations under this Agreement. Any functional changes made by Supplier to its facilities and equipment that impact a Product shall be pre-approved by Customer.

Government Audits. If any governmental agency visits Supplier's facility for a specific complaint or inspection related to any Product, Customer shall be notified immediately. If any samples are taken, Supplier shall collect

duplicate samples from the same lot and location. These duplicate samples shall be sent to Customer within forty-eight (48) hours at Customer's expense. Any written observation from a government agency shall be shared with Customer within three (3) days of receipt of the observation by Supplier. Customer shall have the right to provide input on responses to the agency relating to the Products.

Cooperation. Supplier shall provide Customer with any data and information in Supplier's possession relating to the Products or the facility and its manufacture and quality control procedures that may be reasonably necessary to enable Customer to obtain any governmental approvals.

Indemnification. Supplier shall hold harmless, defend and indemnify Customer for all liability (including reasonable attorneys' fees) arising out of Customer's marketing and sale of the Products, to the extent that such liability is the result of a defect in the Products or otherwise was a result of the manufacturing of the Products.

Regulatory Approval. Supplier has and will have all permits, establishment and facility licenses required by regulatory authorities that are necessary for Supplier to manufacture the Product (including storage thereof) and provide such Product to Customer in accordance with the terms herein. In the event of any change in the raw materials or manufacturing processes solely with respect to the Product that has been requested by Customer, and which change is not required for, or applicable to, any other product which Supplier manufactures or may manufacture, Supplier will be responsible for securing any regulatory approvals that are necessary to implement such change in its facility and Customer will be responsible for securing any regulatory approvals that are necessary to implement such change in the Product. For the purposes of clarification and the avoidance of doubt, if any such change is applicable to, or will impact any other product that Supplier manufactures or may manufacture, then Supplier shall make such change and obtain all necessary regulatory approvals, all at Supplier's expense.

Regulatory Requirements

Regulatory Actions. Supplier shall be responsible for, and shall keep Customer informed of, all FDA regulatory and safety matters regarding the manufacture and sale of the Product. Supplier shall notify Customer before initiating any regulatory action, including a recall, field alert, Product withdrawal or field correction.

Adverse Events. With respect to Products sold or distributed by Customer, Customer shall be solely responsible for voluntarily reporting all serious and unexpected post-marketing adverse events ("AEs") to the FDA. "Life-threatening," "serious" and "unexpected" AEs are defined in accordance with the FDA's definition for such AEs as set forth in 21 CFR 314.80(a). Each of Supplier and Customer shall promptly notify the other party of any adverse drug reactions relating to the Products coming to its attention. Each party shall report to the other all serious AEs that are fatal or life-threatening in 1-calendar day, all other serious AEs in 3-calendar days, and all non-serious AEs in 5-calendar days.

Regulatory Filings. Customer shall promptly make all regulatory filings with the FDA necessary to permit Customer to market and sell the Products under any brand name selected by Customer. Supplier shall obtain and comply with all licenses, permits, consents and applicable laws which may from time to time be required by appropriate governmental authorities with respect to its manufacturing and packaging process and Supplier's facilities, and otherwise to permit the performance of its obligations hereunder.

Regulatory Requirements. Customer shall notify Supplier of all FDA or other regulatory requirements with respect to the copy, labeling and packaging artwork relating to the Product, and any changes in such requirements. Supplier shall not implement any such changes without the prior written consent of Customer.

Product Inspection

Inspection. Customer may inspect the Products processed by Supplier upon receipt thereof and, within thirty (30) business days, shall give Supplier written notice (a "Deficiency Notice") of all claims for Products that deviate from (i) the Product Specifications, (ii) cGMPs, (iii) the terms and conditions of this Agreement, (iv) any applicable legal or regulatory requirement, or (v) that are otherwise negligently produced, in each case in a way that is obvious upon visual inspection. Customer may only provide a Deficiency Notice following this thirty-day period with respect to Products that have latent defects. Upon receipt of a valid Deficiency Notice, Supplier shall either: (a) provide

Customer with a credit; or (b) promptly replace such defective Product.

Product Rejection. Subject to the foregoing provision, Customer shall have the right to reject and return, at Supplier's expense, any portion of any shipment of Products that deviates from the Product Specifications or cGMPs, without invalidating any remainder of such shipment to the extent that such deviation arises from Supplier's failure to provide the manufacturing services in accordance with the Product Specifications or cGMPs.

Recall. In the event any governmental agency having jurisdiction shall request or order, or if Customer shall determine to undertake, any corrective action with respect to Products supplied hereunder, including products containing such Products, including any Product recall, customer notice, restriction, change, corrective action or market action, or any Product change, and the cause or basis of such corrective action is directly attributable to any breach by Supplier of any of its representations, warranties, obligations or covenants contained herein, then Supplier shall be liable, and shall reimburse Customer, for the costs of such action, to the extent such costs arise from Supplier's breach.